

In the Claims:

This listing of claims will replace all prior versions, and listings, of claims in the application.

1. (Currently amended): A method for evaluating the efficacy of a therapeutic agent in the body of a mammal, wherein said agent acts to stimulate apoptosis, ~~which~~ comprises said method comprising:

obtaining a first sample of whole blood, plasma or serum, ~~from a mammal to be treated with said therapeutic agent a sample of a body tissue in which tumor cells are present or a body fluid,~~ wherein said first sample said tissue or fluid can contain a 17 kDa fragment of caspase 3, said fragment produced by specific cleavage of caspase 3 *in vivo*, wherein said first sample has been obtained from said mammal before administration of said therapeutic agent to said mammal;

purifying said first sample using column chromatography;

assaying said first sample to determine the amount of said cleaved 17 kDa fragment of caspase 3 present;

administering said therapeutic agent to said mammal;

obtaining a second sample of whole blood, plasma or serum, ~~said body tissue or said body fluid~~ from said mammal;

purifying said second sample using column chromatography; and

assaying said second sample to determine the amount of said 17kDa fragment of cleaved caspase 3 present;

wherein an increase in the amount of said 17 kDa fragment measured in said second sample over the amount measured in said first sample indicates ~~correlates with~~ apoptosis stimulation and efficacy of said therapeutic agent.

2-4. (Cancelled).

5. (Original): The method of claim 1, wherein said therapeutic agent comprises a chemotherapeutic agent, a radiotherapeutic agent, a tumor suppressing nucleic acid, an oligonucleotide or a combination thereof.

6. (Original): The method of claim 1, wherein said therapeutic agent comprises a nucleic acid.

7. (Original): The method of claim 6, wherein said nucleic acid comprises a DNA molecule which encodes a wild type p53 molecule, an RB molecule, an RB94 molecule, an apoptin molecule or an antisense HER-2.

8. (Original): The method of claim 1, wherein said therapeutic agent is administered as a complex with a ligand-cationic liposome.

9. (Original): The method of claim 8, wherein said ligand comprises transferrin, folate or an anti-transferrin receptor single chain antibody fragment.

10. (Original): The method of claim 8, wherein said ligand comprises an antibody or antibody fragment.

11. (Original): The method of claim 10, wherein said antibody or antibody fragment binds to the transferrin receptor or to HER-2.

12. (Original): The method of claim 10, wherein said antibody fragment is an scFv fragment.

13. (Original): The method of claim 8, wherein said liposome comprises a mixture of dioleoyltrimethylammonium phosphate (DOTAP) and dioleoylphosphatidylethanolamine (DOPE) or cholesterol or a combination thereof or a mixture of dimethyldioctadecylammonium bromide (DDAB) and DOPE or cholesterol or a combination thereof.

14. (Currently Amended): The method of claim 8, wherein said therapeutic agent is further comprises a chemotherapeutic agent or a radiotherapeutic agent.

15. (Currently Amended): The method of claim 1, wherein the amount of said cleaved 17 kDa subunit in said second sample is at least 1.5 ~~to about 2~~ times greater than the amount of said cleaved subunit in said first sample.

16. (Currently Amended): A method for evaluating the efficacy of a therapeutic agent in the body of a mammal, wherein said agent acts to stimulate apoptosis, which comprises:

obtaining a first sample of whole blood, plasma or serum ~~blood or a blood component~~ from a mammal to be treated with said therapeutic agent;

purifying said first sample using column chromatography;

assaying said first sample to determine the amount of a 17 kDa fragment of caspase 3 present in said first sample, said fragment produced by specific cleavage of caspase 3 in vivo;

administering said therapeutic agent to said mammal;

obtaining a second sample of whole blood, plasma or serum ~~blood or a blood component~~ from said mammal;

purifying said second sample using column chromatography; and

assaying said second sample to determine the amount of said 17kDa fragment of cleaved caspase 3 present in said sample;

wherein an increase in the amount of said 17 kDa fragment measured in said second sample over the amount measured in said first sample indicates ~~correlates with~~ apoptosis stimulation and efficacy of said therapeutic agent.

17. (Cancelled).

18. (Original): The method of claim 16, wherein said therapeutic agent comprises a chemotherapeutic agent, a radiotherapeutic agent, a tumor suppressing nucleic acid, an oligonucleotide or a combination thereof.

19. (New): The method of claim 1, wherein said column chromatography comprises P6 or P30 column chromatography

20. (New): The method of claim 1, wherein said mammal is tumor-bearing.

21. (New): The method of claim 16, wherein said column chromatography comprises P6 or P30 column chromatography

22. (New): The method of claim 16, wherein said mammal is tumor-bearing.